The Examiner rejects claims 41-177 under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well established utility.

More specifically, the Examiner contends:

> The utilities cited include diagnostic methods, therapeutic methods, screening methods, antibody production, and as a molecular weight marker. These are not specific, substantial, or well known because there are no disclosed or well known diseases associated with altered levels of KDI expression or any diseases that are treated with KDI polypeptide. Furthermore, there are no specific, substantial or well established utilities connected with the identification of antagonists or agonists of KDI because the use of any antagonists or agonists that may be found to regulate the expression of KDI and the relationship to any specific condition is not disclosed. As for the assertions that the claimed protein can be used to produce antibodies or molecular weight markers, these are not very specific as any protein can be used for these purposes.

(*See,* Paper No. 12, Pages 2-3, Paragraph 3.)

Applicants respectfully disagree and traverse.

A rejection under 35 U.S.C. § 101 is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the Applicant in the written description of the invention. *See* M.P.E.P. §§ 2107.01(II), (III) at 2100-[29-31] (Rev. 1, Feb. 2000). In addition, an Applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. §112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."). *See*, M.P.E.P. at 2100-29. Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. M.P.E.P. § 2107.01(II)(B) at 2100-[29-30].

Further, the Federal Circuit has recently stated with respect to the rejection of claims for lack of utility that:

> The PTO cannot make this type of rejection...unless it has reason to doubt the objective truth of the statements contained in the written description. *See Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441 ("[T]he PTO has the initial burden of challenging a presumptively correct

> assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.")(citations omitted); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971)....The PTO may establish a reason to doubt an invention's asserted utility when the written description "suggest[s] an inherently unbelievable undertaking or involve[s] implausible scientific principles." *Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441; see also *In re Eltgroth*, 419 F.2d 918, 164 USPQ 221 (CCPA 1970) (control of aging process).

In re Cortright, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999). Thus, the initial burden is on the Examiner to establish why one of ordinary skill in the art would *reasonably doubt* Applicants' assertions regarding utility. As discussed below, Applicants submit that the Examiner has not met the necessary burden to establish and maintain a rejection of the claims for lack of utility under 35 U.S.C. §101.

Contrary to the Examiner's comments, Applicants have set forth in the specification statements that clearly and fully describe the function of KDI and explain why Applicants believe the invention is useful. For example, the specification specifically teaches that

> Based on its structural similarity to IFN-omega and its increased expression in response to simulated viral infection, KDI is believed to share many of its biological activities of INF-Omega and other interferon proteins, including, inhibition of tumor proliferation, antiviral activities, NK cell activation and immune system enhancement.

(See, e.g., the specification at page 12, lines 35-38.)

In addition, the specification, at page 124, lines 25-27, teaches that KDI

> . . . can be used clinically for anti-viral therapy, for example, in the treatment of AIDS, viral hepatitis including chronic hepatitis B, hepatitis C, papilloma viruses, viral encephalitis, and in the prophylaxis of rhinitis and respiratory infections.

Applicants submit that these asserted utilities for KDI are specific (*e.g.*, the vast majority of proteins do not have anti-viral activity) and substantial ("the general rule [is] that the treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101." (Revised Interim Utility Guidelines Training Materials, p. 6)). In addition, Applicants submit that these utilities are credible.

These utilities are supported by experimental evidence disclosed in the specification demonstrating the anti-viral activity of KDI. For example, at page 247, line 34 through page 248, line 5 (Example 57), the specification teaches that KDI protects human dermal fibroblasts from infection with encephalomyocarditis virus. Thus, the specification clearly teaches a specific, substantial and credible utility of the claimed polypeptides in anti-viral therapy. This utility is clearly taught by the specification as originally filed and in the patent applications to which the present application claims priority.

With regard to the asserted therapeutic activities, Applicants note that there is no need to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in treating humans where such a utility is asserted. M.P.E.P. § 2107.02 (I) at 2100-[33-34]. All that is required of Applicants is that there be a reasonable correlation between the biological activity and the asserted utility. *See, Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980). Moreover, "[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re Brana, 51* F.3d *1560, 1568* (Fed. Cir. 1995) (emphasis added).

Even assuming, *arguendo*, the Examiner has established a *prima facie* showing that the claimed invention lacks utility, Applicants respectfully submit that they have rebutted the Examiner's showing by proffering sufficient evidence to lead one skilled in the art to conclude that the asserted utilities are more likely than not true. Applicants have directed the Examiner to the specification where clear and specific assertions are made of KDI biological and therapeutic activity.

In view of the above, Applicants submit that the asserted utilities of the invention meet the statutory requirement set forth in 35 U.S.C. § 101. The Examiner has failed to establish and maintain grounds as to why a rejection for lack of utility is proper. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner has also rejected claims 41-177 under 35 U.S.C. § 112, first paragraph, for lack of enablement. In particular, the Examiner contends that "since the claimed invention is not supported by either a specific and substantial asserted utility or a well

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention." *See*, Paper No. 12, Page 3, Paragraph 4.

Applicants respectfully disagree and traverse.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific and substantial or well-established utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. § 101 rejection is proper." M.P.E.P. § 2107(IV) at 2100-28 (Rev.1, Feb. 2000). Therefore, since the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejection of claims under 35 U.S.C. § 112, first paragraph, based on lack of utility of the claimed invention, should be withdrawn.

Conclusion

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. Applicants believe that this application is in condition for substantive examination. If in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below.

Respectfully submitted,

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